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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,612	03/29/2004	Robert E. Carlson	14095.5USU1	4342

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EXAMINER	
SHIBUYA, MARK LANCE	
ART UNIT	PAPER NUMBER
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,612	CARLSON, ROBERT E.	
	Examiner	Art Unit	
	Mark L. Shibuya, Ph.D.	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *10-22,24-27 and 29-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6/22/04; 2/14/05; 5/16/05; 9/26/05; 5/09/06; 5/23/06; 6/15/06; 10/02/06; and 10/12/06.

DETAILED ACTION

1. Application, 10/813,612: Claims 1-22, 24-27, and 29-66 are pending. Claims 10-22, 24-27, and 29-66 are withdrawn. Claims 1-9 are examined.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-9, in the reply filed on 11/06/2006, is acknowledged. The traversal is on the ground(s) that examination of Groups II and III would not constitute an undue administrative burden on examination. The examiner respectfully submits that this is not persuasive because the method of Group I is drawn to methods of making a heterogeneous building block array, which is a materially different function and effects from a method of using an artificial receptor, as in Group II. The method of Group I may be used to make biophobic surfaces, which is a materially different product from the arrays and receptors of Group III. Furthermore, because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search, examination of both invention would impose an undue administrative burden.

3. Applicant's various alternative elections of species in the reply filed 11/07/2006, is acknowledged. Applicant traverses the requirement for elections of species generally on the ground that the inventive concept is independent of any particular structure or species. Applicants assert that all species can be readily searched and examined

together as single groups. This argument is not considered persuasive because the different species are based upon materially different molecular structures and physical principles, and therefore independent search that would entail an undue administrative burden.

Applicant traverses the species requirement for election of the structure of a building block. After further consideration, the requirement is withdrawn.

Applicant elects the species of support that comprises any functional group suitable for coupling to a building block such that the functional group is an amine functional group.

Applicant elects the species of coupling by covalent bond.

4. Claims 10-22, 24-27, and 29-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/07/2006.

Priority

5. This application, 10/813,568, filed 03/29/2004, in the application data sheet, entered 3/29/2004, claims benefit of 60/459,062, filed 3/28/2003; 60/499,776, filed 9/3/2003; 60/499,975, filed 9/3/2003; 60/500,081, filed 9/3/2003; and 60/526,511, filed 12/02/2003.

Information Disclosure Statement

6. The following Information Disclosure Statements (IDS), entered on the dates that follow, have been considered: 6/22/04; 2/14/05; 5/16/05; 9/26/05; 5/09/06; 5/23/06; 6/15/06; 10/02/06; and 10/12/06. However, the citations to Alluri et al., Olivos et al., (both in IDS, filed 6/22/2004) have been crossed off, and the citation Sasmai et al., (IDS filed 2/14/2005), has not been considered because no publication date was included.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and their dependent claims, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: making an array.

Claim 5, and its dependent claims, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: making a receptor surface.

Claim 8, and its dependent claim, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: making an artificial receptor.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Korbel et al., J. Am. Chem. Soc. 2001, 12/20/2000, Vol. 123, 361-362, (IDS entered 5/23/2006).

The claims are drawn to methods of making a heterogeneous building block array, the method comprising: applying building blocks to a solid support in a plurality of spots, the spots comprising 2, 3, 4, 5, or 6 different building blocks; independently

coupling the different building blocks to the solid support in the spots, wherein one or more of the building blocks comprises one or more amino acids; and variations thereof.

Korbel et al., J. Am. Chem. Soc. 2001, Vol. 123, 361-362 (published on the web 12/20/2000), throughout the publication, disclose making an array (Figures 1 and 2) comprising various ratios of D and L amino acids, including serine, which bind in a enantiomer-specific fashion to chiral fluorescent probes (see p. 361, para 2-3, Scheme 1), reading on making a heterogeneous building block array. Korbel et al. teach automated contact printing of nanoliter volumes to spots on a glass slide in a spatially arrayed manner (p. 361, para 2), reading on pin spotting a plurality of spots on a solid support, the spots comprising 2, 3, 4, 5, or 6 different building blocks; and coupling building blocks to the solid support in the spots.

10. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Maly et al., Proc. Natl. Acad. Sci. USA, 3/14/2000, Vol. 97, no. 6, pp. 2419-2424 (IDS entered 6/22/2004).

Maly et al., Proc. Natl. Acad. Sci. USA, 3/14/2000, Vol. 97, no. 6, pp. 2419-2424, throughout the publication, teach a peptide comprising threonine and tyrosine (reading on a building block comprising the formula linker-framework-first recognition element), (p. 2420, para 2, Figure 1, steps 1 and 2; p. 2422, para 1), bound to a well in a microtiter plate via an avidin-biotin linkage (reading on a support, p. 2422, para 1) to a kinase, (reading on a building block, p. 2421-2422, bridging paragraph), to which are

bound inhibitors that are linker structures comprising different linked binding elements, (e.g., Figure 1, Table 2) reading on heterogeneous building blocks.

11. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Shao et al., J. Org. Chem. 1996, Vol. 61, pp. 6086-6087, (IDS entered 6/22/2004).

Shao et al., J. Org. Chem. 1996, Vol. 61, pp. 6086-6087, throughout the publication, disclose making molecular construct of putative receptors comprising linkers, arms, different amino acids (AA, p. 6086, para 4, p. 6087, Table 1) and sometimes a dye attached to the putative receptor (p. 6086, right column), which, in turn, binds to a binding member of an encoded, acetylated tripeptide (including serine) library, wherein the binding member forms a plurality of spots on a polystyrene bead through a linker comprising $(CH_2)_5CO$, thereby forming the spots comprising 2, 3, 4, 5, or 6 different building blocks, wherein the building blocks are coupled to a solid support; and wherein the building blocks have (taken as open, i.e., "comprising" language) the formula linker-framework-(first recognition element)(second recognition element.

12. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Pirrung, Chemical Reviews, 1997, vol. 97, No. 2, pp. 473-488, (IDS entered 06/22/2004).

Pirrung, Chemical Reviews, 1997, vol. 97, No. 2, pp. 473-488, (IDS entered 12/18/2002), throughout the publication, discloses methods of making peptides on 96

microtiter well plates, wherein the amino acids of a peptide can include, for example, serine, tyrosine and threonine (p. 474, Figure 2, reading on 2 or more different, heterogeneous building blocks) that are coupled onto, e.g., microtiter wells (e.g., p. 474, Figure 1) using pin spotting, or spotted onto paper, (pp. 485-486).

13. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Balch, US 6,083,763 A.

Balch, US 6,083,763 A, throughout the patent, and especially at col. 36, line 39-col. 37, line 50, Example IV, discloses methods of forming various biospecific molecules in a well, reading on a spot as claimed, among a plurality of wells on a plate, said plate reading on a solid support. Balch, at col. 37, lines 15-47, teaches, as an example, four different haptens immobilized at different biosites within a single well; and bispecific molecules, specific for one of the said haptens and for different analytes; wherein the hapten-bispecific molecules read on 2, 3, 4, 5, or 6 different building blocks. Balch teaches bispecific ligands that comprise antibodies, which absent evidence to the contrary, would comprise amino acids serine, threonine, and tyrosine (col. 37, lines 9-15). Balch teaches, at col. 9, lines 56-60, different substrates, including glass; at col. 3, lines 44-49, pin spotting; at e.g., col. 30, lines 37-62, teaches printing activated haptens onto an amino-silanized glass surface, reading on a functionalized lawn.

14. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by New et al., WO 01/01140 A1, (IDS entered 05/23/2006).

New et al., WO 01/01140 A1, throughout the publication, and at, e.g., pp. 15-19, 24-26, Examples 1 and 4, p. 15, teach conjugates of amino acids E, Y, Q, S and H, (p. 11), linked to lipids via a serine-glycine spacer, and reading on 2, 3, 4, 5, or 6 different building blocks (e.g., p. 18, p. 16), forming a supramolecular assembly such as a micelle, a lamellar structure, a liposome or other lipid structure (pp. 2-3, bridging paragraph), reading on spots, which are placed in glass vials and then transferred into microtiter plates, reading on arrays on solid supports (e.g., pp. 24-25), and on lawns forming a functionalized lawn coupling building blocks to and on the solid support, for the purpose of making artificial receptors. New et al., at, e.g., p. 2, teach conjugates comprising a head group and a tail group (reading on a linker), wherein the head groups are typically hydrophilic, and contain amino acids, including serine and tyrosine (p. 10-11, and Table 1) and the tail groups are typically hydrophobic, e.g., lipophilic, composed of hydrocarbon chains, halophilic, constructed of fluorocarbon or silane based, and forming a conjugate comprising and reading on a linker-framework-recognition elements, and wherein the linker has the formula $(CH_2)_nC(O)$- (p. 15, stating "[t]he structure of each conjugate is thus: NH_2-headgroup-spacer-amino acid (C_{14} side chain) –amino acid (C_{12} side chain) $–CONH_2$").

15. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/25910 A1, Stålberg.

Stålberg, throughout the publication, and e.g., at p. 8, Example 1, discloses co-immobilizing two different specific ligands that are monoclonal antibodies specific for CK-MB or specific for myoglobin, on a single sensing surface area, to which the ligand may be immobilized through binding with a biocompatible porous matrix, such as a hydrogel, (p. 6, lines 14-26), which reads on the claimed lawn and linker. Absent evidence to the contrary, the antibodies constitute framework and first and second recognition elements, wherein the framework comprises the amino acids serine, threonine and tyrosine.

16. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Lahiri et al., US 20030138853 A1.

The amended claims are drawn to a method of making a heterogeneous building block array, the method comprising: applying building blocks to a solid support in a plurality of spots, each spot comprising 2, 3, 4, 5, or 6 different building blocks; independently coupling the different building blocks to the solid support in the spots; wherein a first spot comprises a first combination of building blocks and a second spot comprises a second combination of building blocks; and variations thereof.

Lahiri et al., US 20030138853 A1, throughout the publication, and especially at the abstract, describe methods of making arrays comprising a plurality of biological

membrane microspots associated with a surface of a substrate, reading on heterogeneous building block array; Lahiri et al., at p. 3, right column-p. 4, left column, describe a method of making microspots comprising multiple different proteins, and Lahiri et al., at pp. 3-4, para [0039], disclose more than one type of protein in each microspot, and G-protein coupled receptors (GPCRs) heterodimers and teach a plurality of different protein on separate microspots, reading on applying building blocks to a solid support in a plurality of spots, each spot comprising at least 2 different building blocks; independently coupling the different building blocks to the solid support in the spots; wherein a first spot comprises a first combination of building blocks and a second spot comprises a second combination of building blocks. Lahiri et al., state:

> [0039] Typically, when the biological membrane microspot comprises a membrane bound protein, only one type of protein is included in each microspot of the array. However, in certain situations more than one type of protein is included in each microspot. For example, some GPCRs heterodimerize for their biological functions. (Angers, S. et al., Proc. Natl. Acad. Sci. USA, 2000, 97, 3684-3689.) In a preferred embodiment of the array, the protein included in the microspot differs from the protein included on a second microspot of the same array. In such an embodiment, a plurality of different proteins are present on separate microspots of the array. Typically the array comprises at least about ten different proteins. Preferably, the array comprises at least about 50 different proteins. More preferably, the array comprises at least about 100 different proteins. Alternative preferred arrays comprise more than about 10^3 different proteins or more than about 10^4 different proteins. The array may even optionally comprise more than about 10^5 different proteins.

Lahiri et al., at para [0039].

Lahiri et al., e.g., at para [0040]-[0041], further teach various numbers of microspots.

Lahiri et al., teach heteromultimers of proteins, which absent evidence to the contrary, read on recognition elements that are hydrogen bond donors and acceptors, and which proteins would inherently have, absent evidence to the contrary, positively and negatively charged recognition units, and would constitute small and bulky recognition elements).

Lahiri et al., state:

> [0040] In one embodiment of the array, each of the microspots of the array comprises a different protein. For instance, an array comprising about 100 microspots could comprise about 100 different proteins. Likewise, an array of about 10,000 microspots could comprise about 10,000 different proteins. In an alternative embodiment, however, each different protein is included on more than one separate microspot on the array. For instance, each different protein may optionally be present on two to six different microspots. An array of the invention, therefore, may comprise about three-thousand microspots, but only comprise about one thousand different proteins since each different protein is present on three different microspots.

Lahiri et al., at para [0040]. Thus Lahiri et al., teach a first spot comprising a first building block and no other, and a second building block but not other.

Lahiri et al., state:

> [0041] In a further alternative embodiment, the array comprises identical microspots or a series of identical microspots that in use are treated with a different analyte (target). For example, an array of the invention can include a "mini array" of 20 microspots, each microspot containing a different membrane bound protein, wherein the mini array is repeated 20 times as part of the larger array.

Lahiri et al., at para [0041]. Thus Lahiri et al., teach a combination of building blocks replicated in a plurality of spots.

Lahiri et al., e.g., at pp. 1-2, in the Summary of the Invention, and p. 4, right column-p. 5, left column, teach coating material reading on a functionalized lawn for

coupling proteins. Lahiri at para [0063], teach pin spotting. Lahiri et al., at para [0085], teach pin spotting on to slides reading on glass plates and microscope slides.

At stated above, Lahiri et al., at para [0039], contemplate protein subunits of heteromultimeric receptors that read upon different building blocks mixed in a spot, (see Lahiri, which states: "However, in certain situations more than one type of protein is included in each microspot. For example, some GPCRs heterodimerize for their biological functions."). There were known in the art, receptors that are heterotrimers, or higher heteromultimers, as evidenced by Evans et al., US 5,990,163, at col. 4, lines 18-40, (teaching heteromultimeric retinoid receptors), so that Lahiri et al., teach methods wherein each comprising 3 or more different building blocks.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 85-105 of copending Application No. 10/244,727; claims 78-92 and 94-96 of copending Application No. 10/727,059; claims 78, 79, 84, 90 and 96-102 of copending Application No. 10/706,505; claims 1-3, 10-15 and 80 of copending Application No. 10/813,568. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of making a heterogeneous building block array, comprising forming a plurality of spots on a solid support, the spots comprising 2, 3, 4, 5 or 6 different building blocks, and coupling building blocks to the solid support in the spots, as in the claims of the instant application, is anticipated by and obvious over the method of making a heterogeneous building block array, the method comprising forming a plurality of spots on a solid support, the spot comprising a plurality of building blocks; and immobilizing building blocks to the support in the spots by covalent coupling, by an ionic interaction, or by a combination thereof, as in the claims of copending Applications No. 10/244,727, 10/727,059, 10/706,505, and 10/813,568.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that following similar claims of related applications, also are subject to the doctrine of obviousness-type double patenting: 10/813,612 (claims 1-9); 10/934,865 (claims 1-10); 10/934,977 (claims 1-9); 11/004,593 (claims 25-32); 11/217,384 (claims

1-6); 10/706,505 (claims 78-84, 87-102); 10/727,059 (claims 78-96); and 11/223,463 (claims 1 and 2).

The examiner respectfully requests applicant's assistance in identifying any other applications subject to double patenting over the claims of the instant application.

Conclusion

19. Claims 1-9 are rejected.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1639